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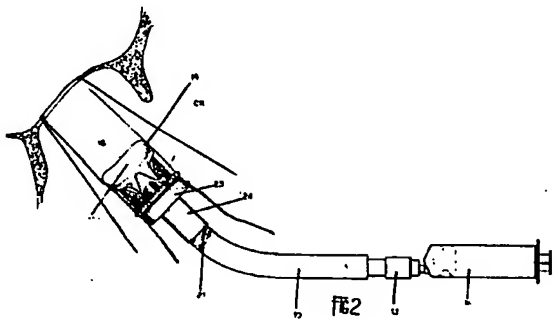
(54) **Surgical instrument for implanting prosthetic heart valves or the like.**

(57) This invention refers to an improved instrument for implanting bioprotheses (CR) in cardio-surgery, comprising an expandable member (18) essentially in the shape of a molar tooth that, in the expanded state, keeps spaced apart the threads (FL) utilized for sewing the bioprothesis in place, while the bioprothesis (CR) is introduced into the patient heart (CC). This avoids that the threads (FL) get hooked to a part of the bioprothesis base (BA) that is usually made from a synthetic material rather rough.

The expandable member in the not-expanded state allows the bioprothesis (CR) to be easily placed and removed from the supporting head (23) of the instrument.

Furthermore the position of the supporting head (23) is adjustable in order to fit the axial dimensions of the bioprotheses (CR) which vary over a wide range.



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TITLE MODIFIED
see front page

INSTRUMENT FOR USE IN SURGERY INTENDED TO RENDER IMPLANTS OF BIOPROTHESES IN HUMAN ORGANS MORE EASY AND SECURE

of Domenico IORIO

The invention refers to an instrument to be employed in surgery and intended to render more easy and secure the implant of bioprotheses in human organs and more particularly the implant of a valvular bioprothesis in mitralic position, and it is in connection with this intervention of high "open heart" surgery that the invention is disclosed and illustrated.

More precisely, the invention concerns an instrument that is an improvement of the instrument subject matter of Italian patent application No. 50586A/79 filed on 16th October 1979, of the same applicant.

As it is known to cardiologists and heart surgeons, serious mitralic alterations are now surgically treated substituting the mitralic valve with a valvular bioprothesis.

This valvular bioprothesis comprises a base or support of a biocompatible syntetic material, as the material sold under the Trade Mark "TEFLON" and three "tabs" of animal origin which constitute the moving parts of the valvular bioprothesis.

The base consists of an annular lower part and three "peaks" circumferentially spaced by 120° and separated by three "saddles" which form together a up-and-down profile to the edges of which the tabs of animal origin are connected.

To fix this bioprothesis in place in the patient's

heart, a number of threads are utilized, one end of which is anchored to the mitralic annulus of the patient that has previously been deprived of the altered mitralic valve. These threads are inserted in a flange provided at the lower annular part of the bioprothesis base and the bioprothesis is caused to slide along the threads until the flange sets against the mitralic annulus to which the same is then sewed by means of the same threads.

This surgical technique has the serious drawback that, during the sliding movement toward the mitralic annulus, one or more threads can get entangled in the bioprothesis support, that has a rough surface, and consequently either a distorsion occurs of the bioprothesis, when the end of the entangled threads are tied, or a faulty connection of the bioprothesis is obtained with the dramatic consequence that the intervention must be repeated.

At present, to avoid this dangerous occurrence, the connection of the bioprothesis to the annulus is inspected from the inside by means of a dentist's mirror. It will be evident that such inspection, under the conditions in which this kind of intervention is carried out, besides being very difficult and inaccurate, unduly protracts the duration of the intervention.

The object of the above mentioned invention of the same applicant was to provide an instrument adapted to support the bioprothesis and having expandable means that, in the not-expanded state, allows the bioprothesis to be placed on the instrument supporting head and removed therefrom, while in the expanded state, it keeps the threads spaced apart from the bioprothesis base, thus avoiding that the threads may got entangled therein.

This previous instrument comprises a rigid tubular body having a fixed head adjacent one end thereof and a small spherical ball of a resilient material fitted on this end, that can be inflated or deflated through the opposite end of the body. To this purpose, the opposite end is provided with a one-way valve and can cooperate with a device adapted to supply air under a slight pressure.

Such instrument, although quite satisfactory, has some drawbacks.

First of all the fixed head supporting the bioprothesis cannot fit the different dimensions of the bioprotheses which, according to the dimension of the heart to which they must be implanted, widely vary both in diameter and height. Particularly the height or axial dimension of the bioprothesis varies considerably as between a minimum of 11 mm and a maximum of 26 mm.

This wide variation of the bioprothesis height results from the fact that the same is proportional to the base diameter which, in turn, is due to the diameter of the mitralic annulus of the patient's heart.

Besides, the spherical shape of the expandable ball did not prove to be optimal, since the outer spherical cap thereof not only is unuseful to its function but it may also constitute an obstacle to the introduction of the bioprothesis in place.

Accordingly, it is an object of the invention to provide an instrument improved in comparison with the object of the previous application mentioned above, wherein the position of the bioprothesis supporting head can be varied with respect to the adjacent end of the rigid body according to the axial dimension of the bioprothesis to be implanted, so that the latter and the expandable member fitted to the adjacent end are in the reciprocally optimal position.

A further object of the invention is to provide an improved instrument having an expandable member having a shape different from the spherical shape. More precisely this member has the truncated shape of a molar tooth that proved to be optimal to the function this member has to perform. This shape can be easily obtained by either forming the expandable member in two parts or in one part only.

The invention will now be described in more details with reference to the attached drawings, in which:

Fig. 1 shows a section of the instrument of the invention with the expandable member in the deflated state;

Fig. 2 is a similar section showing a bioprothesis placed on the instrument, and the particular shape

Fig. 3 is a fragmentary section showing the instrument adjusted for implanting a bioprothesis of a certain height;

Fig. 4 is a similar section showing the instrument adjusted for implanting a much higher bioprothesis than the bioprothesis shown in Fig. 3; and

Fig. 5 shows a perspective view of the base of a valvular bioprothesis to be implanted.

Particularly referring to figures 1 to 4, the instrument of the invention substantially comprises: a tubular body 10, an expandable member 11 the mouth 12 of which is sealingly fitted on one end of body 10. referred to by 13; a supporting member 22 for the bioprothesis cooperating with body 10; a valve 14 placed in the end 15 of body 10 opposite to end 13 supporting member 11; and a device 16, consisting of a syringe (Fig. 2) adapted to be fitted to end 15 for inflating member 11 through the bore of body 10.

Expandable member 11 is generally of the shape of a molar tooth crown of circular cross-section having a flat or slightly concave upper portion and a wall or skirt 19 depending therefrom merging with mouth 12 sealingly fitted over end 13 of body 10 that is provided, to this purpose. with an annular projection 20.

As easily viewed in the drawing, a length 21 of body 10 is externally threaded at a little distance from end 13.

Unlike the instrument disclosed and illustrated in the above mentioned previous application. in the instrument of the invention, support 22 for the bioprothesis is formed separately from body 10 and comprises an annular head 23 having an integrally formed sleeve referred to by 24. havin an inner diameter greater than the outer diameter of body 10. Furthermore. a length 25 og inner surface of sleeve 24 is also threaded so that it can be screwed on threaded length 21 of body 10.

Accordingly, support 22 is assembled to body 10 fitting the latter into sleeve 24 and screwing it onto threaded length 21 whereby the position of annular head 23 can be varied with respect to end 13 of body 10 and the same depends on the entity of the screwing of head 22 onto length 21.

The pitch of matching threads 21 and 25 is very short and consequently the engagement of the two pieces together is irreversible.

By this construction it is possible to adjust the axial position of supporting head 23 on body 10 with respect to end 13, therefore the distance between upper face 26 of head 23 and the base of skirt 19 of expandable member 11 is identical with the height "h" of the bioprothesis measured between base BA of the flange and point PT of cusps CP, i. e. to the axial length of the bioprothesis to be implanted, this height being "h1" in the case of fig. 3 and "h2" in the case of fig. 4, with h2 h1.

In this way, the valvular prothesis carried by annular head 23 is kept exactly in place by expandable member 11, whatever its height can be.

As regards the utilization of the above described instrument, after the insertion of a number of threads FL (fig.2) in the mitralic annulus AM of heart CC of the patient and the insertion of some of them in the annular lower part BA of support CR with member 11 in the deflated condition, end 13 of tubular body 10 of the instrument is fitted in the bioprothesis until lower part BA thereof is placed against upper face 26 of head 23 that will be in an axially inner position.

The point of syringe 16 is then introduced in the bore 15A of body 10 (fig.2) so that air under a slight pressure is injected in expandable member 11 that is inflated. Thereupon supporting head 23 is caused to move toward end 13 by screwing sleeve 24 on thread 21 ir order to lightly clamp the bioprothesis between annular head 23 and skirt 19, as it is clearly illustrated in figures 3 and 4.

As clearly illustrated in fig. 2, the diameter of lateral skirt 19 is substantially identical with the diameter of annular head 23, when member 11 is inflated, accordingly sewing threads FL are kept in tension, clear of support cusps CP and base flange BA of support CR while the bioprothesis is guided to place against the mitralic annulus along threads FL.

Furthermore, since lower part 19A of skirt 19 has a smaller diameter than upper part 19, the points PT of cusps CP are slightly retracted, whereby overhanging

.19 of member 11 is radially projecting with respect thereto, thus avoiding that these points PT can hook sewing threads FL.

Once support CR is inserted in place, i.e. against the mitralic annulus, wherein the valving action is performed by the flaps of animal origin connected to the support, which flaps are not shown. member 11 is deflated acting on valve element 16 with the syringe beak, thus causing the air inflating member 11 to flow out through tubular body 10.

End 13 of the instrument can now be easily taken out of the bioprothesis. that is then sewed to place by means of threads FL.

It is important to note that the bent shape of body 10 is very useful as it allows an easier and better introduction of the bioprothesis. particularly in case wherein the patient undergoing the intervention is affected by an advanced calcification of the mitralic annulus that does not allows the annulus to be exposed at the level of the atrium in order to be easily reached by the surgeon.

In connection thereto it is convenient to point out that angle γ of the bending of the two lengths of body 10 is suitably comprised between 120° and 150°, particularly an angle of 135° proved to be optimal.

As regards the material by which the instrument of the invention is made, it will be a not expensive, biocompatible plastic material, as PVC. This will allow a disposable instrument to be supplied together with the valvular bioprothesis. that is not going to be reutilized, thus avoiding any problem of sterilization.

To the persons skilled in the art it will be evident that the invention is not limited to the shape thereof here described and illustrated and that the same can be made in a different way. provided that the concept is respected of providing an instrument suitable for supporting a valvular bioprothesis for a rapid and secure implant thereof and provided with an end having variable radial dimensions between a reduced dimension allowing an easy placing and removal of the bioprothesis and a maximum dimension, efficient in keeping the sewing threads in tension and clear of the bioprothesis support.

In view of what stated above, all instruments will be in the invention scope, having at one end expandable means, of mechanical, hydraulic or other kind, besides the pneumatic means her, described and illustrated.

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CLAIMS

1. Instrument intended to be used in surgery for implanting a valvular bioprothesis in mitralic position, in the mitralic annulus of a patient's heart, which bioprothesis comprises: a special support (CR) of a synthetic material, substantially consisting of an annular base (BA) and three cusps (CP) with pointed tops (PT) integral therewith, and of three flaps or limbs of a valve of animal origin operatively supported by the support (CR) and is intended to be functionally united to the mitralic annulus, deprived of its own mitralic valve, by means of sewing threads, (FL), previously inserted both in the annulus edge and in a flange integral with the base (BA), which instrument comprises: a tubular body (10) having a first (13) and a second end (15); a supporting means (23) for the bioprothesis adapted to vary its position axially of the first end (13) according to the axial dimensions of the bioprothesis; a member (11) having a circular cross section mounted on the first end (13) and adapted to assume a radially retracted condition when the end (13) has to be fitted in the bioprothesis and taken out thereof, and a radially expanded one wherein the member (11) has a diameter at least equal to the diameter of the supporting head (23) during the operation of introducing the bioprothesis in place in the patient heart (CC), so that the member (11) engage and keeps away said threads (FL) to avoid that the same get entangled in any part of the bioprothesis and especially in its support (CR); and controlling means for the member (11) mounted on the second end (15) of the body (10) for controlling the conditions of the member (11).

2. Instrument according to claim 1, wherein the tubular body (10) has an externally threaded length (21) adjacent to the first end (13), and the supporting means comprises an annular head (23) presenting an upper face (26) receiving the bioprothesis base (BA) and an integral sleeve (24) provided with an internal thread (25) matching thread (21) of the body (10), so that the axial position of supporting head with respect to the first end (13) can be varied and selected screwing sleeve (24) on threaded length (21).

3. Instrument according to claim 1, wherein the body (10) has a bented shape and forms an angle (γ) comprised between 120° and 150° in order to make easier the introduction of the bioprothesis in place.

4. Instrument according to claim 3, wherein the bending angle is 135°.

5. Instrument according to claim 1, wherein said member (11) comprises an inflatable little ball (11) including a flat upper portion (18) and a skirt depending therefrom (19), the mouth (12) of which is sealingly fitted on the first end (13) of the body (10) that holds the supporting means (22) for the bioprothesis, which ball (11), when inflated, is shaped as a molar tooth having such a diameter to engage with the sewing threads (FL), and wherein said body (10) is hollow and has at the second end thereof (15) valve means (14) allowing a gas under a slight pressure to be introduced and extracted therefrom.

6. Instrument according to claim 5, wherein said cotrolling means comprise inflating means (16) for the ball (11) adapted to be connected to the second end (15) of tubolar body (10) and introduce air under a slight pressure therein through valve means (14) and to act on the valve means (14) to cause the air inflating the ball (11) to come out therefrom.

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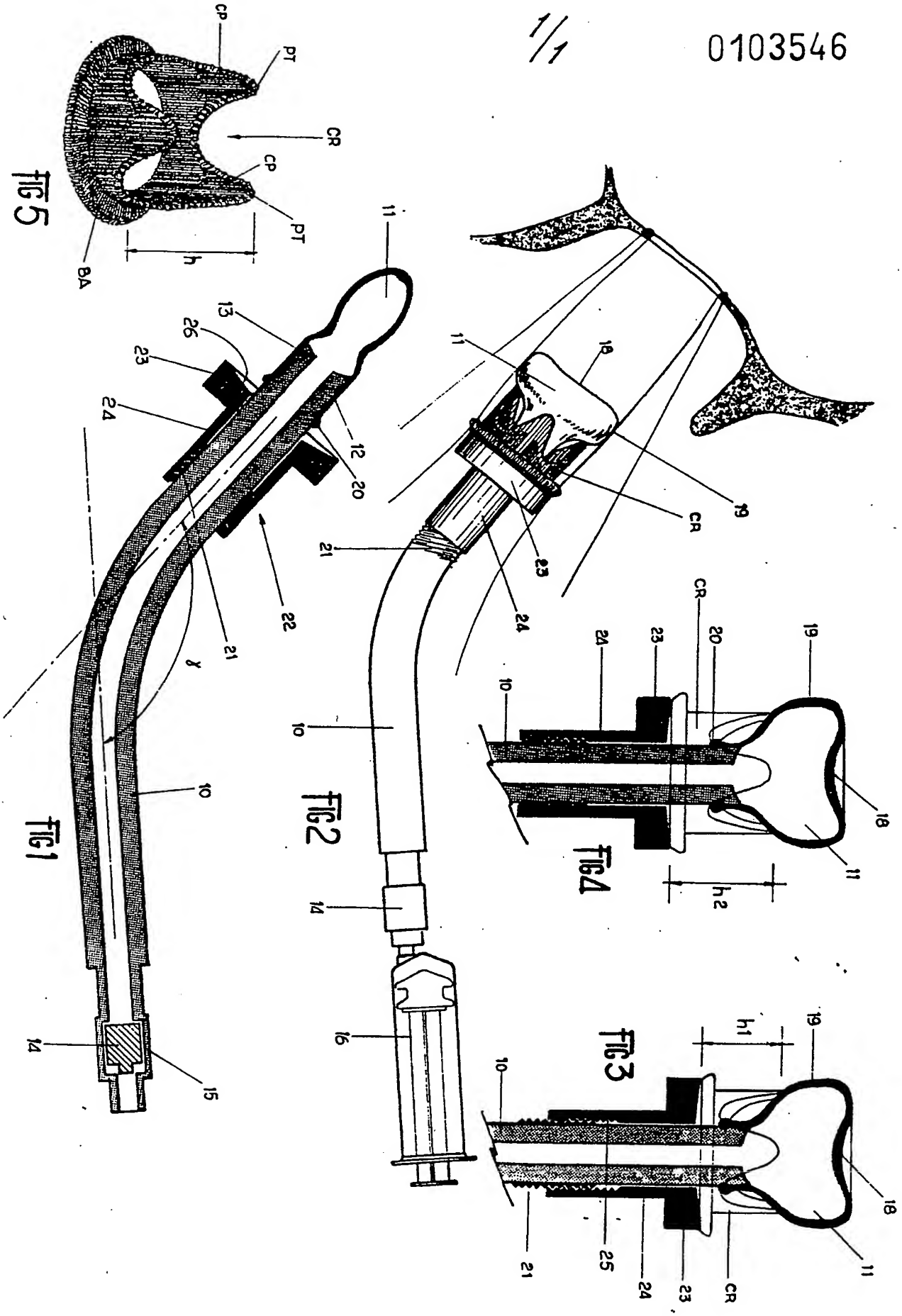
CP
PT
CR
CP
PT
BA
h
FIG 5
11
13
26
23
24
12
20
22
21
γ
10
14
15
FIG 1
11
19
CR
21
23
24
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14
16
FIG 2
CR
24
23
20
19
10
18
11
h2
FIG 4
h1
19
10
18
21
25
24
23
CR
11
FIG 3

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EUROPEAN SEARCH REPORT

Application number

EP 83 83 0164

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl. ³)
A	US-A-3 409 013 (BERRY)		A 61 F 1/22 B 25 B 11/00
A	MECHANICAL ENGINEERING, vol. 89, no. 1, January 1967, page 48 "Heart valve sans suture"		
A	US-A-4 294 141 (MILLER)		

TECHNICAL FIELDS SEARCHED (Int. Cl. ³)

A 61 F
A 61 B
B 25 B

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	14-11-1983	LOWE D.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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E : earlier patent document, but published on, or after the filing date
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